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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE **RECEIVED**

In re Application of: Bandman et al.

JUL 29 2002

Title: VESICLE TRAFFICKING PROTEINS

TECH CENTER 1600/2900

Serial No.: 09/556,178

Filing Date:

April 20, 2000

Examiner: Strzelecka, T.

Group Art Unit:

1637

Box AF

Commissioner for Patents

Washington, D.C. 20231

PETITION UNDER 37 C.F.R. §1.144 FROM REQUIREMENT FOR RESTRICTION

Sir:

This is a Petition under 37 C.F.R. §1.144 to review the Final Restriction Requirement made in the instant case in the Office Action mailed August 13, 2001 and the Final Office Action mailed April 17, 2002. This Petition is filed simultaneously with a Notice of Appeal from the Final Office Action, as allowed under 37 C.F.R. §1.144. Applicants request that the Commissioner vacate the Final Restriction Requirement and require the Examiner, upon searching and examining SEQ ID NO:1 and finding no prior art over which SEQ ID NO:1 can be rejected, to extend the search of the Markush-type claim to include the non-elected species SEQ ID NO:3 and SEQ ID NO:5.

I. FACTS INVOLVED

In Response to a Restriction Requirement mailed May 11, 2001, Applicants elected Claims 1, 2, 16, and 17 directed to polypeptides (Response mailed June 7, 2001). The claims are directed to an isolated polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO:1, SEQ ID NO:3, and SEQ ID NO:5. In addition, the Examiner, in the Restriction Requirement mailed May 11, 2001, required that Applicants elect "a single disclosed species" chosen among SEQ

ID NO:1, SEQ ID NO:3, and SEQ ID NO:5. (Restriction Requirement mailed May 11, 2001, page 4.) In the Response filed June 7, 2001, Applicants stated that “[i]n the event that the Examiner insists upon only examining one of the claimed polypeptides, and therefore requires that only part of Applicants’ claims be elected, Applicants hereby provisionally elect the claims directed to the portion of claims 1, 2, 16, and 17 directed to the polypeptide of SEQ ID NO:1, and the variants and fragments thereof as presently claimed, with traverse.” (Response filed June 7, 2001, page 2, emphasis in original.) The Examiner, in the Office Action mailed August 13, 2001, stated that “Applicants are advised that the sequences presented in claims 1, 2, 16, and 17 are considered as distinct and independent inventions, not species, since SEQ ID NO: 1, 3, and 5 describe three different proteins with different structures and modes of action” and made the Restriction Requirement Final (Office Action mailed August 13, 2001, page 2). Applicants further traversed the Restriction Requirement in the Response filed January 14, 2002, but the Examiner reiterated the Final Restriction Requirement in the Final Office Action mailed April 17, 2002.

II. POINTS TO BE REVIEWED

The Commissioner’s attention is directed to the Patent Office’s own requirements for Markush practice, set forth in the 8th edition of the M.P.E.P. (August 2001) at § 803.02 regarding restriction requirements in Markush-type claims:

PRACTICE RE MARKUSH-TYPE CLAIMS

If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds**

included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry. [emphasis added]

As can be seen from the above, it is clear that the present Restriction Requirement does not meet the Patent Office's own requirements.

First, the number of "members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction." Withdrawal of the restriction requirement as among the **three** specific sequences each in the claims is required on that basis alone.

Second, **"it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. ... Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.**" The polypeptides of the present invention share a common utility in, for example, toxicology studies based on expression profiling.

Third, even if the claims could be considered to be "Markush-type generic claims which include a plurality of alternatively usable substances or members," it is further noted that the M.P.E.P (§ 803.02) states that "A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits." This clearly applies in the present case.

The Examiner attempted to justify the requirement that Applicants choose one among SEQ ID NO:1, SEQ ID NO:3, and SEQ ID NO:5 by alleging that "the sequences presented in claims 1, 2, 16, and 17 are considered as independent and distinct inventions, not species, since SEQ ID NO:1, 3, and 5 describe three different proteins with different structures and modes of action." (Office Action mailed August 13, 2001, page 2.) Applicants submit that the Examiner's allegation that having "independent

and distinct inventions” causes this not to be a “species” election clearly contravenes the procedure outlined above in the M.P.E.P. for examination of Markush-type claims. The M.P.E.P. states that even if a Markush-type claim includes independent and distinct inventions, “the examiner may require a provisional election of a single **species**.” (8th edition of the M.P.E.P. (August 2001) at § 803.02, emphasis added.)

In addition, Applicants submit that examination of all three sequences (SEQ ID NO:1, SEQ ID NO:3, and SEQ ID NO:5) in the instant application would not be an undue burden on the Examiner. In the previous two applications to which the instant case claims priority (United States patent application Serial No. 09/368,408 filed on August 4, 1999, which was itself a divisional application of and claimed priority to United States patent application Serial No. 08/967,364 filed on November 7, 1997), claims to multiple sequences were examined together. In United States patent application Serial No. 08/967,364, claims to polynucleotides encoding SEQ ID NO:1, SEQ ID NO:3, and SEQ ID NO:5 were examined and allowed. In United States patent application Serial No. 09/368,408, claims to methods of detecting polynucleotides encoding SEQ ID NO:1, SEQ ID NO:3, and SEQ ID NO:5 were examined and allowed. The apparent lack of burden on the Examiner in these parent applications, as well as the availability to the Examiner of the results of searches already made in the previous two applications, indicate that there would be no undue burden on the Examiner to examine claims to SEQ ID NO:1, SEQ ID NO:3, and SEQ ID NO:5 in the present application.

III. ACTION REQUESTED

Applicants request that the Commissioner vacate the Final Restriction Requirement and require the Examiner, upon searching and examining SEQ ID NO:1 and finding no prior art over which SEQ ID NO:1 can be rejected, to extend the search of the Markush-type claim to include the non-elected species SEQ ID NO:3 and SEQ ID NO:5.

IV. CONCLUSION

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 09-0108.

Respectfully submitted,

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Date: 17 July 2002

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